

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, *et al.*,
ex rel. MATTHEW A. FITZER, M.D.,

Plaintiffs,

v.

ALLERGAN, INC., *et al.*

Defendants.

Civil Case No. 1:17-cv-00668-SAG

* * * * *

MEMORANDUM OPINION

This Court has, thus far, issued two opinions providing Relator Matthew A. Fitzer (“Relator”) with an analysis of the shortcomings of the allegations in his prior complaints. Despite Defendants’ repeated requests that this Court dismiss Relator’s complaints with prejudice, this Court has allowed him numerous opportunities to amend. Instead of seizing his latest opportunity to amend and moving on to defend his proposed Fourth Amended Complaint (“FAC”), Relator doubles down on his Third Amended Complaint (“TAC”) and asks this Court to reconsider its decision to dismiss the TAC. Relator also asks, in the alternative, for leave to amend.¹

The motion to reconsider presents no new argument or facts and no significant law or facts this Court overlooked or misunderstood. This Court has considered the motion, ECF 120, *see also* ECF 124 (correcting memorandum of law), Defendants’ oppositions, ECF 121, 122, and Relator’s reply, ECF 123, and all of the exhibits attached to those filings. No hearing is necessary. Loc. R.

¹ While Defendants have not admitted that Relator has met the applicable standard for leave to amend, they have elected to contest the FAC at the motion to dismiss stage rather than the motion for leave to amend stage. This Court will, therefore, grant leave to amend without conducting a full analysis of whether the FAC, as a matter of law, meets the legal standard for leave to amend under Federal Rule of Civil Procedure Rule 15.

105.6 (D. Md. 2021). Relator’s motion will be denied insofar as it asks this Court to reconsider its decision dismissing the TAC and granted insofar as it requests leave to amend.

I. FACTUAL BACKGROUND

The relevant facts, derived from the TAC, are set forth in this Court’s March 22, 2022 opinion granting Defendants’ (Allergan, Inc. (“Allergan”) and Apollo Endosurgery, Inc. (“Apollo”)) motions to dismiss the TAC, which brought claims related to Defendants’ alleged violations of the False Claims Act (“FCA”) and the Anti-Kickback Statute (“AKS”).

II. LEGAL STANDARD

Federal Rule of Civil Procedure 54(b) provides that “any order or other decision” that “adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time” before entry of a final judgment. *See also Fayetteville Investors v. Commercial Builders, Inc.*, 936 F.2d 1462, 1469-70 (4th Cir. 1991) (approving the trial court’s reference to Rule 54(b) in reconsidering its ruling on the defendant’s Rule 12(b)(6) motion to dismiss); *Lynn v. Monarch Recovery Mgmt., Inc.*, 953 F. Supp. 2d 612, 618 (D. Md. 2013) (“Motions for reconsideration of an interlocutory order are governed by Federal Rule of Civil Procedure 54(b) . . .”). In this Court, motions for reconsideration must be filed within fourteen days after the Court enters the order. Loc. R. 105.10 (D. Md. 2021).

While the Fourth Circuit has not clarified the precise standard applicable to motions for reconsideration, *Butler v. DirectSAT USA, LLC*, 307 F.R.D. 445, 449 (D. Md. 2015), it has stated that motions for reconsideration “are not subject to the strict standards applicable to motions for reconsideration of a final judgment” under Rules 59(e) and 60(b), *Carrero v. Farrelly*, 310 F. Supp. 3d 581, 584 (D. Md. 2018) (quoting *Am. Canoe Ass’n v. Murphy Farms, Inc.*, 326 F.3d 505,

514 (4th Cir. 2003)); *see Fayetteville Investors*, 936 F.2d at 1470 (expressing “vigorous[] disagree[ment]” with a trial court’s use of a Rule 60(b) standard in reconsidering its previous order on a Rule 12(b)(6) motion). However, courts in this District frequently look to the standards used to adjudicate Rule 59(e) and 60(b) motions for guidance when considering Rule 54(b) motions for reconsideration. *Carrero*, 310 F. Supp. 3d at 584; *Butler*, 307 F.R.D. at 449; *Cohens v. Md. Dep’t of Human Resources*, 933 F. Supp. 2d 735, 741 (D. Md. 2013); *see also Fayetteville Investors*, 936 F.2d at 1470 (positively discussing a district court’s reference, but not strict adherence, to the Rule 60(b) standards in reconsidering its prior ruling) (citing *Gridley v. Cleveland Pneumatic Co.*, 127 F.R.D. 102 (M.D. Pa. 1989)).

Motions to amend final judgments under Rule 59(e) may only be granted “(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice.” *Hutchinson v. Staton*, 994 F.2d 1076, 1081 (4th Cir. 1993). Further, Federal Rule of Civil Procedure 60(b) explicitly provides that a court may only afford a party relief from a final judgment if one of the following is present: “(1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence; (3) fraud or misconduct by the opposing party; (4) voidness; (5) satisfaction; or (6) any other reason that justifies relief.” In light of this guidance, “[m]ost courts have adhered to a fairly narrow set of grounds on which to reconsider their interlocutory orders and opinions.” *Blanch v. Chubb & Sons, Inc.*, 124 F. Supp. 3d 622, 629 (D. Md. 2015); *see also id.* (“Courts will reconsider an interlocutory order in the following situations: (1) there has been an intervening change in controlling law; (2) there is additional evidence that was not previously available; or (3) the prior decision was based on clear error or would work manifest injustice.” (quoting *Nana-Akua Takyiwaa Shalom v. Payless Shoesource Worldwide*, 921 F. Supp. 2d 470, 481 (D. Md. 2013))).

As a general matter, “a motion to reconsider is not a license to reargue the merits or present new evidence’ that was previously available to the movant.” *Carrero*, 310 F. Supp. 3d at 584 (quoting *Royal Ins. Co. of Am. v. Miles & Stockbridge, P.C.*, 142 F. Supp. 2d 676, 677 n.1 (D. Md. 2001)). Ultimately, the decision to reconsider interlocutory orders rests in this Court’s “broad discretion.” *Am. Canoe Ass’n*, 326 F.3d at 515.

III. ANALYSIS

Relator argues this Court committed two “clear errors” in its decision dismissing the TAC. First, Relator argues that this Court misapplied the Fourth Circuit’s decision in *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013) by conflating the two distinct avenues it describes to plead that a false claim was presented to the government for reimbursement. Second, Relator argues that this Court erred by applying an overly strict causation standard rooted in an evidentiary burden that can only apply at the summary judgment stage. These issues will be addressed in turn.

A. Presentment

Relator correctly states that “[t]he Fourth Circuit in *Nathan* adopted a hybrid approach, synthesizing the standards articulated in several other circuits to provide *two* different methods for establishing presentment.”² ECF 120-1 at 11 (emphasis in original). That approach allows Relators to plead an FCA case in two ways:

First, a plaintiff can allege with particularity that specific false claims actually were presented to the government for payment. This standard requires the plaintiff to, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby. Alternatively, a plaintiff can allege a pattern of conduct that

² This Court acknowledges, as Relator points out, that it mistakenly referred to *Nathan* as an AKS-based FCA case. ECF 120-1 at 17 n.6. Relator is correct that *Nathan* was not an AKS case, but that changes nothing about this Court’s analysis or its application of *Nathan* to this case.

would *necessarily* have led to submission of false claims to the government for payment.

United States ex rel. Grant v. United Airlines Inc., 912 F.3d 190, 197 (4th Cir. 2018) (internal quotations and citations omitted) (emphasis in original). If a relator seeks to allege presentment under the second avenue, Rule 9(b)'s particularity requirement requires "that plaintiffs connect the dots, even if unsupported by precise documentation, between the alleged false claims and government payment." *Id.* at 199.

Relator acknowledges that this Court "cited the proper dual standard in *Nathan* and *Grant*" but he argues that it "conflated the two methods in its analysis and applied them in a stricter fashion than the standards demand." ECF 1210-1 at 18. Relator clings to his argument that he has met both methods of presentment.

i. Method 1: Specific False Claims

As indicated above, the first method requires a Relator to allege with particularity that "specific false claims actually were presented" by, at a minimum, describing "the time, place, and contents of the false representation, as well as the identity of the person making the misrepresentation and what he obtained thereby." *Grant*, 912 F.3d at 197. According to Relator, his "2013 (Allergan) and 2014 (Apollo) tables present just that. They identify specific providers, the states where they practice, and a count of LAP-BAND procedures per year." ECF 120-1. None of that identifies a specific false *claim* or the requisite allegations sufficient to satisfy Rule 9(b)'s requirements. First, the tables do not specify the "time" of the alleged false representation. All the TAC says is that the physicians listed in the tables "appeared on Defendants' physician locator tool in 2013" or 2014. ECF 100 ¶¶ 319-20. That gives no information about when any surgeon apparently submitted a false claim and, thereby, made a "false representation."

This Court explained this deficiency in its opinion dismissing the TAC. ECF 118 at 13 (“The tables also omit other important information about the purported claims, like the dates on which the relevant procedures were performed and the dates on which each claim was submitted for reimbursement.”). Nonetheless, Relator accuses this Court of improperly “relying on” *United States ex rel. Dugan v. ADT Sec. Servs. Inc.*, No. DKC-2003-3486, 2009 WL 3232080, at *14 (D. Md. Sept. 29, 2009), which predated *Nathan*. ECF 120-1 at 21. This Court did not “rely on” *Dugan*—it cited that case for the extremely basic proposition that “Rule 9(b) requires a Plaintiff to allege with particularity the dates of the supposed fraudulent conduct.” ECF 118 at 13. This point is uncontroversial—even assuming *Dugan* is inapplicable because it predates *Nathan*, both *Nathan* and *Grant* stand for the same general point for which the Court cited *Dugan*. *Grant*, 912 F.3d at 197. In order to allege that a specific false claim was actually submitted for reimbursement, Relator must describe, among other details, the “time” of the false representation. *Id.* Ironically, Relator argues that he “needs only the claims’ year of service to tie them to the taint of the kickback scheme[.]” ECF 120-1 at 21. But the TAC does not even allege that much—it merely alleges that the listed surgeons appeared on the physician locator in either 2013 or 2014, which provides no temporal details about any of the statistical information in the tables.³ ECF 100 ¶¶ 319-20. Relator argues that the TAC *did* allege dates of service and accuses this Court of committing error by failing to acknowledge those allegations. ECF 123 at 6 n.4. According to Relator, “[p]rior to providing the tables of claims data, the Third Amended Complaint alleged that providers listed on the locator were ‘simultaneously being reimbursed by Medicare for LAP-BAND implantation

³ The fact that Relator’s proposed FAC adds a sentence attempting to clarify that “[t]he following table includes Medicare paid claims *with dates of service in 2013*” lends further support to this Court’s conclusion that the TAC was deficient on this front. ECF 120-4 at 63 (emphasis added).

procedures.’” *Id.* First, that misstates the TAC. What the TAC actually alleges is that “[s]everal of the providers that Defendants remunerated” (*i.e.* presumably not *all* and without giving any information about who these “several” providers are) “were simultaneously being reimbursed by Medicare” for LAP-BAND surgeries. ECF 100 ¶ 315. Second, even if all of the surgeons listed in the tables were “simultaneously” being reimbursed, the TAC gives no information about when the surgeries, and/or the corresponding “simultaneous” reimbursements, occurred. Again, the only temporal information the TAC offers is that the listed surgeons appeared on the physician locator in either 2013 or 2014.

Second, the TAC does not adequately allege the “contents of the false representation” because it contains no fact-based allegations that the surgeries reflected in the tables were LAP-BAND surgeries rather than REALIZE band surgeries, and, therefore, no allegation that the claims for reimbursement corresponded to LAP-BAND surgeries. Relator insists that the TAC “explains how Relator knows these claims actually relate to LAP-BAND specific procedures.” ECF 120-1. The TAC alleges that the physicians listed in the tables “exclusively performed LAP-BAND surgeries” and asserts that the listed physicians “were not qualified to perform [surgeries to implant] the one alternative device, the REALIZE device[.]” ECF 100 ¶¶ 319-20, 50 n.15. But the only fact on which Relator relies to support that conclusion is that there are device-specific qualification requirements to perform gastric banding surgeries. ECF 120-1 at 16 n.12. That fact, even assumed true, does not lead to the conclusion that the surgeons listed in the tables were not qualified to perform REALIZE band surgeries, nor does it lead to the conclusion that the surgeries referenced in the tables were LAP-BAND surgeries. Simply put, the fact that the listed surgeons were qualified to perform LAP-BAND surgeries, and allegedly performed enough of those surgeries at some point to be listed on the locator tool in 2013 or 2014, says nothing about whether

the surgeries and claims listed in the tables correspond to LAP-BAND surgeries or REALIZE band surgeries. This Court has assumed the truth of Relator’s factual assertion that there are device-specific qualification requirements for different forms of gastric banding procedures, as well as his factual assertion that the surgeons listed in the tables appeared on the physician locator tool in 2013 and/or 2014. But from those facts alone Relator jumps to the conclusion that the surgeons listed on the tables were *not* qualified to perform REALIZE band surgeries, and that they *exclusively* performed LAP-BAND surgeries. This Court will not, and indeed cannot under Rule 9(b), assume the truth of that unsupported conclusion. Contrary to Relator’s repeated assertions, the TAC does not “explain[] how Relator *knows* these claims actually relate to LAP-BAND specific procedures”—it merely explains that he has *concluded* they do.⁴ ECF 120-1 at 16 (emphasis added).

This Court explained all of these deficiencies in its March 22, 2022 opinion, and it explained why those deficiencies prevented the Court from being able to determine whether the purported claims in the tables were “actual, representative, false claims.” ECF 118 at 13. Despite these explanations, Relator suggests that this Court was construing *Nathan* and *Grant* to require

⁴ On this point, the FAC again displays the irony of this motion for reconsideration. Over and over again, Relator has alleged and argued that the surgeons listed in the tables in the TAC were not qualified to perform REALIZE band surgeries. *See* ECF 100 at 50 n.15. As it turns out, though, the FAC alleges that Relator removed one of the surgeons from the tables after doing more research and discovering that the surgeon may have been REALIZE band certified after all. Surprisingly, notwithstanding that admission in the FAC, Relator continues to argue in this motion that the surgeons listed in the tables in the TAC were “not Realize certified[.]” ECF 120-1 at 22. To be clear, this Court is not applying a standard at this stage that is meant to assess whether Relator’s allegations are *correct*. Many “factual” allegations that support well-pleaded complaints ultimately prove untrue. And if this case proceeds through discovery, Relator may be able to prove his theory that the listed surgeons only performed LAP-BAND surgeries, or he may not. But to survive a motion to dismiss, he must allege *facts* that, taken as true, support his theory. He may not simply espouse that theory, relying on facts that do not support it, and ask this Court to credit its truth.

Relator to “submit an executed form CMS-1500 in order to present a claim.” ECF 120-1 at 18. That is not true, and this Court’s March 22, 2022 opinion comes nowhere close to such a finding. This Court does not read *Nathan* or *Grant* to require a relator to file an executed claim form in order to meet the “specific false claim” method of pleading presentment. All this Court held was that the deficiencies described above prevent this Court from adopting Relator’s assertion that the purported claims reflected in the TAC’s tables are “specific false claims [that] actually were presented to the government for payment.” *Grant*, 912 F.3d at 197.

ii. Method 2: Pattern of Conduct

The second method of pleading presentment requires a relator to “allege a pattern of conduct that would *necessarily* have led to submission of false claims to the government for payment.” *Id.* (emphasis in original). Relator argues that this Court “conflated” this method with the first method described above because it “made its holding under the second method ‘for similar reasons’ as the first[.]” ECF 123 at 6.

It is simply not legal error, as Relator suggests, to rely on some of the same reasoning that supported this Court’s analysis on “method 1” as support for its analysis on “method 2.” Some of the same deficiencies that left this Court unable to find that the TAC pled “specific” claims—namely, that the TAC gives no information about when any services were provided or when any corresponding claims were submitted, and that the TAC fails to adequately allege that the claims data it provides corresponds to LAP-BAND surgeries—prevents this Court from concluding that the allegedly fraudulent scheme “would have *necessarily* led to a false claim being submitted to the government for payment.” *Grant*, 912 F.3d at 198. Without any of this information, the TAC does not “connect the dots . . . between the alleged false claims and government payment.” *Id.* at 199.

But this Court’s analysis did not stop there. It went on to compare this case to *Nathan*, and two cases cited by *Nathan*: *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009) and *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720 (1st Cir. 2007). Ultimately, this Court concluded that “[t]he TAC’s allegations here are much closer to the speculative allegations that were determined insufficient in *Rost* and *Nathan* than the more concrete, fact-based, allegations in *Duxbury* that did not require the district court to assume the truth of the relator’s unsupported inferences.” ECF 118 at 15-16. Instead, as this Court explained, the TAC asked this Court “to blindly accept [Relator’s] conclusory assertions that because several surgeons submitted reimbursement requests at unspecified times, for surgeries that took place at unspecified times, using a Medicare code that is not specific to LAP-BAND procedures, that false claims were *necessarily* submitted for reimbursement.” *Id.* at 16 (emphasis in original). In this Court’s view, those analytical gaps left open the possibility that the allegedly fraudulent scheme did not *necessarily* lead to the presentment of false claims. That possibility, this Court found, was similar to the possibility in *Rost* (credited by *Nathan*) that “physicians prescribed [the drug] for off-label uses only where the patients paid for it themselves or when the patients’ private insurers paid for it.” *Nathan*, 707 F.3d at 460 (quoting *Rost*, 507 F.3d at 733) (alteration in original).

Relator now relies on *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017), which it never cited in its opposition to Defendants’ motions to dismiss the TAC, and he increases his reliance on *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009), which was cited once but was not discussed in his opposition. Neither case is controlling, and both are distinguishable. As Relator points out, in *Nargol*, the First Circuit analyzed a flexible approach to pleading presentment which is similar to the Fourth Circuit’s “necessarily presented” standard. There, however, the court held that “the complaint essentially

alleges facts showing that it is statistically certain that DePuy caused third parties to submit many false claims to the government[.]” *Nargol*, 865 F.3d at 41. The TAC’s allegations fall well short of alleging to a degree of “statistical certainty” that false claims were submitted. *Grubbs* provides little guidance here because of its distinct facts. There, the relator alleged a fraudulent billing scheme in which doctors were lying on their bills about having performed face-to-face hospital visits, when in fact they had not. *Grubbs*, 565 F.3d at 184. The Fifth Circuit held that if a relator “cannot allege the details of an actually submitted false claim, [he] may nevertheless survive by alleging particular details of *a scheme to submit false claims* paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *Id.* at 190 (emphasis added). Here, Relator does not allege a scheme *to submit false claims*, he alleges a marketing scheme designed to generate sales of a product, which, in his view, led to the presentment of false claims. Moreover, as explained above, this Court has not found that the TAC alleges “reliable indicia that lead to a strong inference that claims were actually submitted.” *Id.*

To be sure, Relator disagrees with this Court’s analysis, and he is certainly entitled to that view. The Fourth Circuit has only had a few occasions to articulate the precise contours of the “necessarily presented” method of presentment. And even when it has, those explanations have not always been unified. Indeed, much like Relator argues here, Judge Keenan in *Grant* argued that the majority’s standard unfairly required “that a relator allege direct evidence of presentment at the pleading stage[.]” *Grant*, 912 F.3d at 204 (Keenan, J., concurring in part and dissenting in part). While this Court does not read the “necessarily presented” standard to require allegations of direct evidence (as the *Grant* majority clarified in response to Judge Keenan’s concern), the test is admittedly, and by design, strict. And while Relator may disagree, in this Court’s view, the

Fourth Circuit and the other courts to which this Court cited have held that complaints with the kinds of analytical gaps included in the TAC fail to meet the “necessarily presented” standard.

This Court did not conflate the two methods of pleading presentment. It recognized and considered both methods, albeit with some overlapping analysis. In the end, though, this Court explained its reasoning for why it found that the TAC failed to plead presentment under either distinct method. Despite Relator’s disagreement with that finding, this Court finds no “clear error” in its prior opinion.

B. Causation

Relator also argues this Court committed two errors in its causation analysis. First, he argues that this Court erroneously relied on the “particular patient” standard from the Third Circuit’s decision in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 100 (3d Cir. 2018). Second, he argues that the Court erroneously held that Relator failed to allege surgeons’ knowledge of their own locator listings.

i. Relator’s Burden to Plead Causation

With respect to the “particular plaintiff” standard, this Court acknowledges that the standard is applicable (to the extent it applies in the Fourth Circuit at all), as an evidentiary burden of production at the summary judgment stage. This Court did not intend to impose that evidentiary burden on Relator at the pleading stage, but meant to explain the causation standard in an AKS-based FCA case, and then explain why the TAC does not allege facts that, taken as true, can plausibly meet that standard.

As the opinion made clear, this Court’s discussion of *Greenfield* was prompted by the parties’ disagreement about the applicable standard of causation in an AKS-based FCA case. That dispute was important, of course, because the applicable standard of causation *on the merits*

informs Relator's burden *at the pleading stage*. For example, if a particular claim has a "but-for" causation requirement on the merits, the plaintiff must plead facts that lead to a plausible inference that the plaintiff can satisfy that causation requirement at the merits stage (once the case gets there), assuming the facts alleged prove true.

Here, the parties disagreed on the applicable standard. Defendants advocated for a "but-for" cause standard. ECF 118 at 17. Relator, for his part, advocated for a standard that he called a "proximate cause" standard but that, in this Court's view, stretched beyond traditional notions of "proximate cause" and would have "categorically include[d] any and all claims 'tainted' by an AKS violation." *Id.* The state of the law on causation in AKS-based FCA cases, particularly in the Fourth Circuit, is unsettled, and both parties were, therefore, perfectly free to argue for their preferred standard. But in response to those arguments, this Court explained that, in its view, both sides were wrong. *Id.* at 17-18. As this Court explained, every court to consider Defendants' proposed "but-for" cause standard has rejected it. *Id.* On the other hand, though, "courts have also rejected the attempt Relator makes to stretch the proximate cause standard[.]" *Id.*

Having rejected both sides' proposed standards, this Court was left to explain what, in its view, is the correct causation standard in an AKS-based FCA case. This Court explained that "several courts have 'articulated a middle of the road approach.'" *Id.* (quoting *United States v. Teva Pharmaceuticals USA, Inc.*, No. 13 Civ. 3702 (CM), 2019 WL 1245656, at *24 (S.D.N.Y. Feb. 27, 2019)). This is where the Court turned to *Greenfield* and its conclusion that "a kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Greenfield*, 880 F.3d at 100. Then, after explaining the "middle of the road" causation standard, this Court quoted a case on which Relator relied that summarized the standard as follows:

“Relators need only show that the [defendants’] referral . . . actually sat in the causal chain.” *Teva Pharmaceuticals*, 2019 WL 1245656, at *24.

At this point, the Court went on to explain why, in its view, the TAC did not allege facts that, taken as true, lead to a plausible inference that Relator would be able to establish that the unlawful referrals he alleges “‘actually sat in the causal chain’ between the alleged AKS violation and the allegedly false claim.” ECF 118 at 18-19 (quoting *Teva Pharmaceuticals*, 2019 WL 1245656, at *24). While this Court should have been more specific by explicitly acknowledging the difference between Relator’s burden here (at the pleading stage) and the evidentiary burden that was at issue in the cases this Court discussed, its analysis did not hold Relator to any evidentiary burden. Although this Court referenced the “particular patient” phrase from *Greenfield* several times, the Court did not mean to suggest that Relator must *identify* a “particular patient” in his complaint or conclusively link a “particular patient” to a particular false claim. Rather, as Relator acknowledges, he must allege “more than mere correlation to establish causation[.]” ECF 120-1 at 28. This Court’s opinion made clear he did not do that. He did not adequately allege that the purportedly false claims on which he relied were related to LAP-BAND surgeries; he did not adequately allege that anyone was subject to an unlawful referral, primarily because he did not provide any temporal information about when any referrals were made, when any procedures took place, or when any claim was submitted; and he did not adequately allege that any of the providers listed in the claims tables were aware of the alleged kickback. Without any of this information, this Court explained that the TAC’s *allegations* did not adequately link the alleged AKS violations to the alleged false claims in a way that could create a plausible inference that any referrals by the surgeons listed on the physician locator “‘actually sat in the causal chain’ between the alleged

AKS violation and the allegedly false claim.” ECF 118 at 18-19 (quoting *Teva Pharmaceuticals*, 2019 WL 1245656, at *24). Put differently, the TAC alleges mere correlation, not causation.

Relator also argues that this Court ignored a table in the TAC that “bolsters the causal link beyond a simple temporal proximity” because it shows that a few surgeons apparently performed more LAP-BAND surgeries in 2013 than they did in 2012. ECF 120-1 at 32. Even assuming the table leads to a plausible inference that the alleged kickback scheme increased these surgeons’ use of the LAP-BAND in 2013, the table does not support Relator’s argument on the causation element because it does not draw any link between the kickback scheme and any *false claims*.

Finally, Relator argues that this Court “erroneously held that Relator failed to allege surgeons’ knowledge of locator listings.” ECF 120-1 at 33. According to Relator, he “can find no authority requiring [a] plaintiff-relator [to] establish *non-parties*’ knowledge of the scheme for any purpose. The FCA only requires that *Defendants* know about the fraud.” *Id.* (emphasis in original).

This argument simply mischaracterizes this Court’s opinion. This Court did not hold that Relator needs to allege, or ever prove, any surgeons’ knowledge of “the scheme” or of “the fraud.” *Id.* All this Court found is that the TAC does not adequately allege that any of the physicians listed in the tables provided in the TAC knew that they appeared on the physician locator and were, therefore, aware that they had received the alleged kickback. ECF 118 at 19-20. This finding supported the Court’s broader conclusion that the TAC did not adequately allege the requisite causal link between the alleged kickback scheme and any allegedly false claims. As the cases this Court discussed make clear, the causation element requires something more than a showing that a claim was merely “tainted” by an AKS violation but something less than a showing that the provider would not have made the referral but for the kickback. At a minimum, this standard

appears to require that the relevant provider in an AKS-based FCA case was aware of the alleged kickback. Otherwise, in this Court's view, if a provider submitted a claim for reimbursement without knowing he or she had received a kickback, the claim would merely be "tainted" by the AKS violation. And as explained above, that is not enough of a causal link between the AKS violation and the alleged false claim. As the *Greenfield* court explained:

A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient. Even if we assume Accredo paid illegal kickbacks, *that is not enough to establish that the underlying medical care to any of the 24 patients was connected to a breach of the Anti-Kickback Statute*; we must have some record evidence that shows a link between the alleged kickbacks and the medical care received by at least one of Accredo's 24 federally insured patients.

Greenfield, 880 F.3d at 100 (emphasis added). Mindful that *Greenfield* is a summary judgment case, all this Court has found is that the TAC does not adequately allege that any relevant providers were aware of the kickbacks they allegedly received. That finding, in turn, supports this Court's conclusion that the TAC does not allege enough facts that, even when assumed true, can meet the causation requirement.

IV. CONCLUSION

For the reasons set forth above, Relator's motion, ECF 120, will be GRANTED in part and DENIED in part. The motion will be DENIED insofar as Relator requests reconsideration, and GRANTED insofar as he requests leave to amend. The Clerk's office will be directed to docket the Fourth Amended Complaint. A separate order follows.

Dated: May 18, 2022

_____/s/
Stephanie A. Gallagher
United States District Judge